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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,174	10/23/2003	Kenneth L. Rinehart	4126-4012	2597

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EXAMINER

COOK, REBECCA

ART UNIT PAPER NUMBER

1614

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/693,174

Applicant(s)

RINEHART ET AL.

Examiner

Rebecca Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-30 and 32-38 is/are pending in the application.
4a) Of the above claim(s) 36-38 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 19-30 and 32-35 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-8 and 31 are canceled. Claims 36-38 are withdrawn as not reading on the elected invention. Claims 19-30 and 32-35 are examined.

In view of the amended title and abstract the earlier objections to them are withdrawn.

Election/Restrictions

Applicants remarks are noted.

Claim Rejections - 35 USC § 112

Claims 19-30 and 32-35 are again rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons given in the Paper of December 15, 2004. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that one of ordinary skill would recognize that the instant hydroxyl and/or amino substituents of the recited compounds can be converted to function groups which are readily lost upon administration to a human, and that a patent need not teach what is well known in the art, such as prodrugs. However, these are not described in the specification and the recited prodrugs are not limited to them. Furthermore, in a lecture at the PTO in 2005 (cited for evidentiary purposes) Dr. Scott Hecker emphasized that it is well-known in the art that discovering prodrugs is not easy.

Applicants argue that the "additional drug for combination therapy" is not the point of novelty and the "comprising" language allows that the claims can contain any additional component. This is not persuasive. The specification discloses (pages 6-7) that the intent is only to form compositions for the treatment of cancer.

Since claim 31 has been canceled its rejection under 35 USC 112, paragraph two is moot.

Claim Rejections - 35 USC § 102 and 103 Withdrawn

Upon reconsideration the rejection of claims 19-21, 24 and 26-28 under 35 U.S.C. 102(b) as being anticipated by EP 381 514 is withdrawn.

Upon reconsideration the rejection of claims 22-23, 25, 29-30, 32-33 and 35 under 35 U.S.C. 103(a) as being unpatentable over EP 381 514 is withdrawn.

Prior Art of Record

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. PubMed (Dickens) discloses that an alkane acts as a pro-drug to yield the alkene, but does not render the instant invention obvious in the absence of additional information. The Chemical Basis of Drug Activity discloses the activation of alkenes to epoxides and the metabolism of alcohols to carbonyls, but does not render the instant invention obvious in the absence of additional information.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-30 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,800,661 for the reason given in the Paper of December 14, 2004. Applicants' arguments that the instant claims are of differing scope from those of the '661 patent are not persuasive. If the claims were of the same scope a statutory double patenting rejection would have been made under 35 USC 101. The instant method of treating cancer includes treating the cancers of '661 and the instant compounds are the compounds of '661. Therefore, the method of treating cancer of '661 renders the instant method obvious.

Information Disclosure Statement

Applicants' remarks regarding Palmeta are noted. However, it is not available in the parent file.

Action IS Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook



Primary Examiner
Art Unit 1614

August 16, 2005